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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,454	09/15/2003	James D. Murray	UCAL-286	4027
24353	7590	06/04/2004	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP			ALONZO, NORMA LYN	
200 MIDDLEFIELD RD				
SUITE 200			ART UNIT	
MENLO PARK, CA 94025			PAPER NUMBER	
			1632	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/663,454

Applicant(s)

MURRAY ET AL.

Examiner

Norma C Alonzo

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claims 1-30 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-8, 13-21, drawn to a non-human transgenic animal and method of making said transgenic animal, classified in class 800, and subclass 14.
 - II. Claims 9-12, drawn to an expression cassette comprising a coding sequence for a stearyl-coA desaturase linked to a tissue-specific promoter, classified in class 435, subclass 320.1.
 - III. Claims 22, 23, 24, 27-30, drawn to a food product harvested or processed from a non-human transgenic animal wherein the food product is milk, classified in class 426, subclass 34.
 - IV. Claims 22, 23, 25, 27-30, drawn to a food product harvested or processed from a non-human transgenic animal wherein the food product is meat, classified in class 426, subclass 105.
 - V. Claims 22, 23, 26, 27-30, drawn to a food product harvested or processed from a non-human transgenic animal wherein the food product is an egg, classified in class 426, subclass 47.
3. Claims 22 and 23 link(s) inventions Groups III-V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 22 and 23. Upon the allowance of the linking claim(s), the restriction

requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to two different products. Group I is directed to a non-human transgenic animal and methods for making said non-human transgenic animal. Group II is directed to an expression cassette. The two inventions have different chemical and physical structure, mode of action and function. For example, the structure of a nucleic acid is distinct from that of an animal comprising the nucleic acid. While the vector of group II could be used for making the transgenic animal of group I, it can be used in other unrelated processes such as *in vitro*

expression of proteins. Likewise, the animal of group I can be produced by using a different vector than that of group II. Therefore, group I and II are patentably distinct inventions.

5. Inventions III-V are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different products. Group III is directed to milk food products harvested or processed from a non-human transgenic animal. Group IV is directed to meat food products harvested or processed from a non-human transgenic animal. Group V is directed to egg food products harvested or processed from a non-human transgenic animal. While groups III-V claim dependency on the non-human transgenic animal of claim I, the inventions have different chemical and physical structure, mode of action and function. The inventions could be derived from sources other than a single transgenic animal. For example, the animal source of the food product directed by group V, egg food products, must be different from the animal source of the food product directed by group III, milk food products, because the only source of egg food products is poultry, which is generally not a source of milk products. In the case of group III and IV, milk products could be harvested from a transgenic goat, while meat food products could be obtained from a transgenic cow. Further, group IV and group V are different inventions because they are drawn to different products. For example, the meat food products directed by group

IV could be harvested or processed from a transgenic cow, whereas the egg food product directed by group V could be harvested or processed from a transgenic chicken. Therefore, groups III, IV, and V are different, each from the other and patentably distinct.

6. Inventions I-II and III-V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case groups I and II direct to a non-human transgenic animal and method of making said transgenic animal and an expression cassette comprising a coding sequence for stearyl-coA that could be used to generate said transgenic animal. Groups III-V direct to food products harvested or processed from a non-human transgenic animal wherein the food products are milk, meat or an egg. The groups are different because the process claimed could be used to make other and materially different products. For example, the non-human transgenic animal claimed in group I could be used to generate an animal model of stearyl-coA overexpression for screening pharmaceutical compounds or cells from the non-human transgenic animal encoding the transgene for stearyl-coA could be utilized to establish primary cell cultures for experimentation.

Further, the products claimed can be made by another and materially different process. Groups III-V claim food products harvested or processed from a non-human

transgenic animal comprising a transgene encoding a fatty acid desaturase. Group I directs to a non-human transgenic animal comprising a transgene encoding stearyl-CoA. The food products claimed by groups III-V could, for example, be harvested or processed from a non-human transgenic animal comprising a transgene encoding Delta 12 fatty acid desaturase or omega-3 fatty acid desaturase.

In addition, the invention of group II is directed to an expression cassette comprising the coding sequence for stearyl-coA desaturase linked to a mammary specific promoter or to an intestinal epithelium specific promoter. The non-human transgenic animal of group I from which milk, meat or egg food products could be harvested or processed from as claimed in groups III-V, could be generated using a vector other than said vector of group II. For example, a vector comprising a non-specific epithelial promoter or smooth muscle cell promoter may generate a non-human transgenic animal from which milk, meat or egg food products expressing the stearyl-coA transgene could be harvested from.

Therefore, the groups I and II and III-V are directed to different inventions and are patentably distinct.


6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Norma C Alonzo whose telephone number is 571-272-2910. The examiner can normally be reached on 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NCA



RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER